

REMARKS

Claims 44, 48-53 and 55 are all the claims pending in the application.

Initially, Applicants thank the Examiner for the March 10, 2004 interview, and further thank the Examiner for his comments and suggestions. In response to the interview, Applicants provide the following remarks.

(1) In the March 10, 2004 interview, the Examiner suggested that the language “irritancy or inflammatory characteristics” be removed from claim 44.

Claim 44 has been amended to cancel the phrase “irritancy or inflammatory characteristics” as suggested by the Examiner.

(2) In the March 10, 2004 interview, the Examiner stated that claim 44 should recite a step of subtracting background levels of mediator release from the total measurement.

Applicants submit that independent claim 44 currently accounts for background levels of mediator release, and therefore, claim 44 need not be amended as suggested. Specifically, claim 44 recites in step (b) “detecting release of at least one mast cell and/or basophil cell mediator in response to said exposing.” Since step (b) recites detecting mediator release only in response to exposure of the cell to the substance or chemical, the measurement does not include that release which is not in response to the exposure (i.e. background). Therefore, Applicants submit that the Examiner’s comments concerning background levels are not relevant to the patentability of claims 44, 48-53 and 55, and accordingly, claim 44 need not be amended as suggested.

(3) The Examiner asserted in the May 9, 2003 Office Action, that claims 44, and 47-54 are not enabled because one could not confirm the potential allergenicity of compounds that stimulate IgE independent release from mast cells, since one could not determine whether mediator release was IgE dependent or independent when a sensitizing agent (IgE specific for the test compound) was present.

Applicants submit that, although one skilled in the art is capable of determining whether a mediator release is IgE dependent or independent, the claimed assay is a screening assay. As such, a confirmation step is not essential to the assay and need not be recited in the claims. Accordingly, applicants submit that the Examiner's comments are not relevant to the patentability of claims 44, 48-53, and 55.

In view of the Amendment filed November 10, 2003, and further in view of the above, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections. Reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Mark L. Hayman
Registration No. 51,793

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: March 26, 2004